Ethical Principles for Learning Health Care System

Description for the General Public

The main principle of the so-called “learning health care systems” is a deep integration of biomedical research involving human beings and medical practice. Within a computerized learning health care system, a patient is at the same time a participant of biomedical research, while a physician not only cures diseases, but also tests hypotheses and collects data. The main goal of a learning health care system is to quickly identify and apply more effective, safer treatment, more precise diagnosis and more accurate prophylaxis. In short: learning health care systems speed up the development of medical science! Learning health care systems are not a project for distant future, they are already in place, just now. So should we hesitate to further introduce them? Should we have any doubts?

Imagine such a situation: we want to compare efficacy and safety of two different pharmaceutics: drug A and drug Z. In the course of routine scientific practice, we compare performance of patients taking drug A and Z. The patients are randomly appointed to each group. In everyday medical practice, on the other hand, a doctor deals with a concrete situation: a patient may have already been on drug A, with little effect. Drug A may have caused some unpleasant side effects and the doctor wants to check now how Z would work. In a learning health care system, the doctor and the patient do not have a choice – the system makes the choice for them. Doctors can only observe the results of randomly prescribed therapy. We see that in learning health care systems patient’s individual best interests may be trumped by interests of patients as a group. In our project we ask: is this moral?

Let’s consider a different example: at present, participation in a randomized clinical trial is voluntary and every participant has to read and sign an informed consent form before entering a medical experiment. In a learning health care system, on the other hand, involvement in low-risk clinical trials may be obligatory. It does not mean, of course, that someone would force a patient to take a specific therapy. But a possible solution in case of patient’s refusal could be lack of reimbursement for the therapy – the patient will pay for himself. Shortly: no reimbursement for those who want to be free-riders in a learning health care system. In our project, we will ask the same question again: is this morally acceptable?

As one researcher put it, learning health care systems put medical sciences on turbo. Computers, large databases, special software make learning in medical sciences really rapid and that brings benefits to everyone: patients quickly get safe and effective therapies, doctors gain new scientifically proven knowledge, state pays less for more efficient medical care. But before we introduce learning health care systems a few ethical questions have to be answered: What is the difference between biomedical experiments and medical practice? Does it matter? Should participation in biomedical research be obligatory? To what extent may individual rights be compromised for the sake of common good? Who should be the patient’s guardian within a learning health care system? There are many more such ethical questions and our project aims at clearly formulating and answering them.